Notice of Allowability	Application No.	Applicant(s)	
	09/869,049	KATO ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *31 October 2005*.

2. ☒ The allowed claim(s) is/are *99-119*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *12.21.2005* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Examiner's Amendements/ Comments

1. Your application has been re-assigned to Art Unit 1655 at the United States Patent and Trademark Office (i.e., USPTO). The assigned Examiner to your application at the USPTO is Dr. Kailash. C. Srivastava. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1655.

2. Request for continued examination (i.e., RCE) under 37 CFR §1.114, including the fee set forth in 37 CFR §1.17(e), was filed in this application on 31 October 2005 after a the Notice of Appeal filed 28 August 2005. Since this application is eligible for continued examination under 37 CFR §1.114, and the fee set forth in 37 CFR §1.17(e) has been timely paid, the Notice of Appeal filed 28 August 2005 has been withdrawn pursuant to 37 CFR §1.114. Applicants' submission filed on 31 October 2005 has been entered. Accordingly, an RCE has been established and the action on RCE follows.

3. Applicants' response and amendment filed 31 October 2005 to Office Action mailed 2/28/2005 is acknowledged and entered.

CLAIMS STATUS

4. Claims 2-3, 5-20 and 22-80 are cancelled.

5. Claims. 81-98 are added.

6. Claims 1, 4, and 21 are amended.

7. Claims 1, 4, 21 and 81-98 are pending and are examined on merits.

Examiner's Amendment

8. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicants, an amendment may be filed as provided by 37 CFR §1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

9. Authorization for this Examiner's amendment was given in a telephone interview with Mr. William I. Solomon on 9 December 2005.

In the Claims:

- Cancel Claims 1, 4, 21, and 81-98:
- Add new Claims 99-119 as follows:

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99. (New) A pharmaceutical preparation comprising a compound (I), which is obtained by reacting a peptide (II) having a free amino group, with a sugar (III) having reducing power and selected from group A, wherein said peptide is a pharmaceutical compound,

wherein group A consists of lactose, sialyllactose and compounds prepared by chemically binding a polymer from the group consisting of polyoxyethylene, polyglutamic acid and polyvinylpyrrolidone to a hydroxyl group other than the hydroxyl group formed from the reducing aldehyde group of lactose and sialyllactose,

wherein an amino group of said peptide (II) reacts with an aldehyde group in said sugar (III); and

wherein said compound (I) can release said peptide (II) having a free amino group in response to changes in pH.

100. (New) The preparation according to claim 99, wherein said peptide (II) is insulin.

101. (New) The preparation according to claim 99, wherein said peptide (II) is enkephalin.

102. (New) The preparation according to claim 99, wherein said compound (I) is in a pharmaceutical carrier obtained by the following steps:

said peptide (II) is combined with a pharmaceutical carrier, to obtain a peptide-carrier composition, and said peptide-carrier composition is reacted with said sugar (III) to give said preparation comprising said compound (I).

103 (New) The preparation according to claim 99, wherein said compound (I) is in a pharmaceutical carrier obtained by the following steps:

said peptide (II) is reacted with said sugar (III) to give said compound (I), and said compound (I) is combined with a pharmaceutical carrier.

104. (New) The preparation according to claim 99, wherein said compound (I) is encapsulated in a pharmaceutical carrier obtained by the following steps:

said peptide (II) and said sugar (III) are encapsulated in a pharmaceutical carrier, and said peptide (II) is reacted with said sugar (III) to give said compound

(I) in said pharmaceutical carrier.

105. (New) The preparation according to claim 99, wherein said compound (I) is encapsulated in a pharmaceutical carrier obtained by the following steps:

said peptide (II) is reacted with said sugar (III) to give said compound (I), and said compound (I) is encapsulated in said pharmaceutical carrier.

106. (New) The preparation according to any one of claims 102-105, wherein said pharmaceutical carrier is selected from the group consisting of liposome, lipid emulsion, microemulsion, polymer micelle, microcapsule, microsphere and magnetic particles.

107. (New) The preparation according to claim 99, wherein said group A consists of lactose and sialyllactose.

108. (New) The preparation according to any one of claims 102-105, wherein said group A consists of lactose and sialyllactose.

109. (New) The preparation according to claim 106, wherein said group A consists of lactose and sialyllactose.

110. (New) The preparation according to claim 100, wherein said compound (I) is in a pharmaceutical carrier obtained by the following steps:

insulin is combined with a pharmaceutical carrier, to obtain an insulin-carrier composition, and said insulin-carrier composition is reacted with said

sugar (III) to give said preparation comprising said compound (I).

111. (New) The preparation according to claim 100, wherein said compound (I) is in a pharmaceutical carrier obtained by the following steps:

insulin is reacted with said sugar (III) to give said compound (I), and said compound (I) is combined with a pharmaceutical carrier.

112. (New) The preparation according to claim 100, wherein said compound (I) is encapsulated in a pharmaceutical carrier obtained by the following steps:

insulin and said sugar (III) are encapsulated in a pharmaceutical carrier, and said insulin is reacted with said sugar (III) to give said compound (I) in said pharmaceutical carrier.

113. (New) The preparation according to claim 100, wherein said compound (I) is encapsulated in a pharmaceutical carrier obtained by the following steps:

insulin is reacted with said sugar (III) to give said compound (I), and said compound (I) is encapsulated in said pharmaceutical carrier.

114. (New) The preparation according to any one of claims 110-113, wherein said pharmaceutical carrier is selected from the group consisting of liposome, lipid emulsion, microemulsion, polymer micelle, microcapsule, microsphere and magnetic particles.

115. (New) The preparation according to claim 101, wherein said compound (I)

is in a pharmaceutical carrier obtained by the following steps:

enkephalin is combined with a pharmaceutical carrier, to obtain an enkephalin-carrier composition, and said enkephalin-carrier composition is reacted with said sugar (III) to give said preparation comprising said compound (I).

116. (New) The preparation according to claim 101, wherein said compound (I) is in a pharmaceutical carrier obtained by the following steps:

enkephalin is reacted with said sugar (III) to give said compound (I), and said compound (I) is combined with a pharmaceutical carrier.

117. (New) The preparation according to claim 101, wherein said compound (I) is encapsulated in a pharmaceutical carrier obtained by the following steps:

enkephalin and said sugar (III) are encapsulated in a pharmaceutical carrier, and said enkephalin is reacted with said sugar (III) to give said compound (I) in said pharmaceutical carrier.

118. (New) The preparation according to claim 101, wherein said compound (I) is encapsulated in a pharmaceutical carrier obtained by the following steps:

enkephalin is reacted with said sugar (III) to give said compound (I), and said compound (I) is encapsulated in said pharmaceutical carrier.

119. (New) The preparation according to any one of claims 115-118, wherein said pharmaceutical carrier is selected from the group consisting of liposome,

lipid emulsion, microemulsion, polymer micelle, microcapsule, microsphere and magnetic particles.

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Examiner's Statement of Reasons for Allowance

10. The following is Examiner's statement of reasons for allowance:

The closest prior art are:

Sessler et al. (U.S. Patent 5,580,543);

Katsukiyo (JP-07-061999); and

Masashi et al (JP 9-263579).

The presently claimed invention comprising a pharmaceutical composition produced via reacting a peptide having a free amino group with lactose or sialyl lactose or compounds wherein lactose or sialyl lactose are chemically bound to a polymer among polyoxyethylene, polyglutamic acid, and polyvinylpyrrolidone via the hydroxyl group other than the hydroxyl group formed from the reducing aldehyde group of lactose or sialyllactose is not taught by any of the references cited *supra* either individually or in combination.

Thus, none of the art cited *supra* alone or in combination teach or reasonably suggest to obtain a pharmaceutical composition produced via reacting a peptide having a free amino group with lactose or sialyl lactose or compounds wherein lactose or sialyl lactose are either chemically bound to a polymer among those recited in the claimed invention, or lactose or sialyllactose are bound to said polymers according to the method recited in the claimed invention.

Any comments considered necessary by applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

11. Claims 99-119 are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

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Patent Examiner
Art Unit 1655
(571) 272-0923

December 22, 2005

JON WEBER
SUPERVISORY PATENT EXAMINER